HEALTH MATTERS
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Give automatic approval to drugs recognised in advanced countries

LAST week healthcare activists claiming to act on behalf of SA's sickest and most vulnerable marched to the Department of Trade and Industry to demand changes to SA's patent laws. For over a decade these activists have been lobbying government to "Fix the Patent Laws" in a misguided attempt to improve access to medicines. Unfortunately for patients who desperately need life-saving drugs, the activists have been knocking on the wrong door and barking up the wrong tree, to mix some metaphors. The activists' argument about "evergreening" is as tiresome as it is wrong. Activists repeatedly accuse innovative pharmaceutical companies of making minor variations to existing drugs on which they hold a patent in order to "extend" patent terms, commonly referred to as "evergreening". This allegation, however, is unfounded as patents cannot be extended under the current laws. A patent lasts for a maximum of 20 years. After that time, a drug goes into the public domain and competitors are free to copy and financially benefit from the sale of the copied drug.

If, within that 20-year period, as often happens, the company holding the patent, discovers a new way to make the medicine, or to deliver it, or to reduce the pill burden, it then has to file for an entirely new patent application based on the new invention or process. If the innovator company is granted a new patent on the basis of a reformulated drug, this is solely because the reformation is, in fact, a novel invention and meets the requirements for inventiveness as adjudicated in a South African court of law. Those who believe that patents can be "evergreened" may claim that the new patent is simply an "extension" of a patent on an older drug, but this is not so. As soon as the original patent expires, generic companies are free to produce the older version of a drug. However, generic companies that are interested in competing in the market, obviously, for commercial reasons, would prefer to copy the newer improved version of the drug.

According to the Department of Health (DoH) Annual Report for 2014, one of the strategic objectives it has set for the drug registration authority, the Medicines Control Council (MCC), is to "improve the registration timelines of medicines through capacity development". The MCC's targeted registration timelines were "28 months for new chemical entities (NCEs) and 30 months for generics". Depressingly, the latter is up from the targeted 15 months depicted in the 2013 Annual Report. Moreover, the 2014 Annual Report reveals that the actual average registration period for generics was 37 months (up from 34 months in 2013) and for NCEs 38 months (up from 36 months in 2013). Thus, in an age of tremendous scientific and medical progress that offers new hope to South African patients, the regulator failed to approve both generic and NCEs in a timely manner and is getting worse. The DOH's explanation was as follows: "The timelines were not achieved due to the limited number of evaluators available to review submissions". Apart from shifting the goal posts and failing to meet its targets, the DoH

has also employed a shameful new tactic. Surprisingly, or perhaps not, the DoH has stopped publishing the indicator on the average registration timelines for all drugs and in the most recent 2015 Annual Report introduced a new indicator that only provides data on "prioritised medicines" (antiretroviral, oncology, TB medicines and vaccines) and has significantly altered the performance indicator. Now, it only looks at approving 70 percent of prioritised medicines within 22 months for NCEs and 15 months for generics. The MCC cannot even approve prioritised medicines in a timely manner, curtly explaining that "old medicines applications dated from the 1990's still in system. Unable to comply with current regulatory requirements. Lack of experienced and skilled valuators (sic)". To make matters worse many of these drugs that are simply not reaching the market due to MCC incompetence have already been approved by advanced country drug regulators. The MCC would do us all a favour, increase access to medicines and allow us to leap-frog up the developmental ladder if it recognised drug approvals by advanced country drug regulators, granting them automatic approval in SA. The primary aim of this proposal is to reduce the time period for patients in South Africa to have access to the latest available technologies.

Delaying access to proven, effective drugs results in pain, suffering and perhaps even death. There are other factors that have a bearing on patient access to quality care and treatment in our country, but our ability to reform the current drug review process ranks among those most easily achieved - but only if SA's Minister of Health demonstrates the compassion and the foresight, and sufficient political will to see it through. SA has experienced some well-documented stock-outs of essential medicines in public clinics. These stock-outs have nothing whatsoever to do with patents, but are due instead to numerous failures that exist throughout the complex continuum of healthcare in SA's government-run system. "Fixing patent laws" in SA will do nothing to increase access to life-saving drugs when we know that patients at government-run establishments cannot even access cheap off-patent medicines. Activists ought to be focusing their attentions on the real barriers hampering access to medicines and pressuring the South African government to improve its regulatory environment.

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Jasson Urbach: BDlive, 5 October 2016

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